National Center for Research Resources
National Institutes of Health
Department of Health and Human Services

Division of Research Infrastructure

Site Visit Information And Instructions for the Research Centers in Minority Institutions (G12) Program

December 2006

An Administrative Document Issued by the
National Center for Research Resources (NCRR)

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RCMI REVIEW AND SITE VISIT GUIDELINES

I. Overall Review Structure

Both new and competing renewal RCMI applications are peer-reviewed, which typically includes a site visit, followed by review of the site visit report and final scoring of the application by the parent RCMI-IDeA review committee. NCRR staff determines the need for a site visit. Special Emphasis Panels are used to conduct all portions of the peer review for applications that have a committee member conflict or based on other administrative issues; in these cases the RCMI-IDeA review committee has limited involvement and the SEP determines the final score at the site visit. The NCRR Advisory Council, prior to funding, conducts the second level of review in terms of appropriateness of the peer review process and within the framework of programmatic priorities and funding strategies.

The peer review evaluates both scientific and technical merit of the RCMI infrastructure and proposed scientific pilot projects if such projects are presented in the application. Evaluation of infrastructure components is based on the appropriateness and the likelihood of achieving of the RCMI goals in terms of the overall mission of the RCMI program to increase biomedical capacity. The contribution of the requested/supported cores and other resources should be relevant to these goals. The suitability of the proposed scientific projects in advancing the investigators' careers and in achieving research independence is also evaluated. Inclusion of requests for facilities, major equipment, and/or additional faculty throughout the grant period should be justified based on a description of need and plans for the future use of the resource consistent with the stated RCMI goals.

II. Site Visit Agenda and Logistics

Site Visit Purpose: The site visit review group functions as a fact-finding team. The site visitors must be thorough in their efforts to obtain all information necessary for a fair and adequate evaluation of the proposal based on the individual needs of the institutional infrastructure plan. The site visit must be a friendly, non-adversarial, fact-finding mission. Each segment of Day 1 of the site visit is an opportunity for the site visitors to interact with the applicants. Breaks and lunches are good times for discussions with RCMI personnel in terms of follow up to the presentations or with those personnel who are not presenting formally.

The site visit agenda is developed in consultations between the NCRR Scientific Review Administrator (SRA) at NCRR and the RCMI Program Director (PD). The following chart illustrates a typical site-visit agenda, which is applicable to most RCMI Programs, and is subject to change depending on the requirements of each RCMI application.

RCMI Site Visit Agenda Template

DAY 1 - AM	On Site
7:00	Meet in lobby of hotel for transportation to the site
7:15 – 8:00	Executive Session 1: Orientation, questions/answers-site visitors only
8:15 – 8:30	University Officials
8:30 – 9:15	Program Director
9:15 – 10:45	Core Presentations
10:45 –11:00	Break
11:00 –	Administrative Reviewer meets with RCMI Administrators
11:00 –12:30	Scientific Project Presentations
Day 1 - PM	**On Site**
12:30 – 1:30	Working Lunch
1:30 – 2:30	Tour of Facilities
2:30 – 3:30	Scientific Project Presentations (if needed)
3:30 – 4:00	Wrap up by Program Director
4:00 – 4:15	Break
4:15 – 6:00	Executive Session 2: Review of Presented Pilot Projects; site visit team only
DAY 2 - AM	**Off Site**
7:30 – 11:30	Executive Session 3: Infrastructure Review; site visit team only

Reviewer Preparation for Site Visit: Each member of the site visit team should arrive at the site visit with written critiques of their assigned section(s). Information presented in the written application as well as that gathered at the site visit will be used in the peer review of an RCMI application. At the site visit, you should modify the review you wrote prior to coming to the site visit to take into account additional information presented at the site visit, as well as the discussion of the site-visit team. You will be expected to provide an electronic version of your final critique(s) to the SRA either at the end of or within one week after the site visit. The recommendations (critiques) of the site visit team are formatted into a site visit report to be considered by the RCMI-IDeA review

committee for final review and scoring of the RCMI application. Please edit your written review accordingly, and give it to the SRA by the close of the meeting on the second day if possible.

Site Visit Team Composition: The site visit team is composed of RCMI-IDeA review committee members, one of whom typically serves as the Chairperson–unless the site visit is a Special Emphasis Panel (SEP), in which case the Chairperson cannot be a current member of the RCMI-IDeA review committee. The team also includes reviewers with specific expertise in the particular areas of research described in the application and an administrative reviewer, who covers general administration and financial management of the RCMI program and other financial-related matters. During the scientific presentations, the administrative reviewer will meet with institutional representatives, the RCMI Administrative Manager, and any other relevant RCMI staff members.

A Scientific Review Administrator (SRA) from the NCRR Office of Review (OR) is responsible for planning and coordinating the necessary administrative steps for the site-visit. S/he facilitates communications between the applicant and the site-visit team; instructs the site visitors in their duties; oversees the process and conduct of the review; communicates review policy; collects review materials generated by members of the site-visit team; and formulates the site-visit report for the RCMI-IDeA Review Committee. An NCRR Grants Management Specialist may also be present at the site visit. In addition, a program officer from the NCRR Division of Research Infrastructure attends the site visit as an observer and, when called upon by the SRA, provides interpretation of program policies.

Responsibilities of the Site Visit Chairperson: The Chairperson serves as moderator, conducts the executive sessions, and assumes primary responsibility for presenting the application and the report of the site-visit team to the next meeting of the RCMI-IDeA Review Committee. The Chairperson of the site-visit team is usually a member of the RCMI-IDeA Review Committee. It is expected that the Chairperson is to become thoroughly familiar with the entire application prior to coming to the site visit.

During the presentations at the open sessions of the site visit, the Chairperson moderates the flow of the presentations, makes sure that the presenters adhere to the predetermined schedule, and assures that presenters allow adequate time for questions. At the end of each presentation, the Chairperson invites the members of the site-visit team to address questions to the presenter on issues that need further clarification.

During Executive Sessions 1 and 2 of the site visit, the Chairperson moderates the discussion of the scientific, program, core and other infrastructure presentations. S/he also decides when to limit additional discussion on each topic and proceed to scoring or voting. The Chairperson or administrative reviewer leads the discussion on the budget, assuring that recommended deletions and/or reductions from the requested budget are specific and clear.

Site Visit Review Team Executive session 1: This session will take place on site with only the site visitors in the room. During this session, the SRA will provide orientation to the site visit agenda and goals of the site visit. The team members are expected to ask questions of procedure at this time. Also, if the site visit team wishes to speak with any relevant applicant staff member who is not already on the agenda or if any additional materials or reports are needed, the site visitors should make these requests at this time so that the SRA can make the necessary arrangements with the applicants to meet have the applicant staff available either by phone or in person; the SRA also will obtain the requested materials from the applicant and distribute copies to all site visitors.

Site Visit Review Team Executive session 2: This session will take place on site at the end of the first day. The assigned reviewer of each presented pilot project will present his/her critique, including evaluations of scientific merit and need for the RCMI resources. Following these presentations, and discussion by the site visit team, each reviewer will score each of the presented projects, with a score for Scientific Merit. If major questions remain regarding a project, the site visit team may request further clarifications from appropriate RCMI personnel, such as the Program Director, administrative staff, or investigators, who may return to discuss issues with the team.

Site Visit Review Team Executive session 3: This session is held at the hotel, occurring on the morning of the second day. At this session, reviews of the infrastructure sections including Program Directorship, RCMI Advisory Committees, and Core Laboratories and Activities are presented by the assigned reviewers and discussed by the site visit team. Each of these sections is scored using the NIH scale from 1-5. The team then votes on the number of years recommended if a vote for no further consideration is not approved.

The final task of the site visit team is to make a consensus recommendation on each of the items requested in the budget. During the time that this final executive session is held, the Program Director and administrative management personnel should be readily available to address any questions raised by reviewers.

Site Visit Presentations: The Institution will decide on the particular presentations to be covered at the site visit. These presentations will occur on Day 1, but the PI/PD are encouraged to be available at least by telephone throughout the 1.5 days of the site visit. All presentations should adhere to the time slots suggested in the Site Visit Agenda template, always leaving sufficient time for questions from the site visit team. An overview of the specific goals is provided for the types of presentations in the following sections. Specific review criteria and scoring instructions/tables follow these overviews.

RCMI Administration: About two-and-a-half hours (8:15 -10:45 a.m.) are for presentations by the Program Director and other administrators. The Program Director provides the SRA with the agenda prior to the site visit, organizing the presentations in a way that he/she believes will best represent and showcase their RCMI. Introductory presentations from high-level University officials should occur first and should not exceed 15 minutes total, with a few minutes included for any questions from the site visit team. It is suggested that the Program Director use the remaining time during this session

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to provide an overview of the RCMI Program. This section typically includes an institutional overview, planning and goal setting; program administration; and any other components of the RCMI review. At least 15 minutes of this time should remain for questions at the end of the presentation.

Core Laboratories and Other Infrastructure Resources: Major cores and other RCMI resources should be presented at the site visit. The number and length of these presentations may vary within the scheduled time frame. Resource management, personnel, utilization, and prioritization processes should be described, including support of specific RCMI-supported projects and how these resources expand the biomedical capability of the institution should be described. Justification of the request in terms of need and budget should be provided as well.

Pilot Projects: These scientific presentations should be no longer than 15 minutes, allowing an additional 15 minutes for discussion by the site visitors with the presenting investigators and their research team members, as applicable. The research plan should be described and new or additional information since submission of the application. Each presentation should include a quantitative description of which RCMI resources will be used for the research project and a justification for requested resources. For each presentation, reviewers will evaluate the scientific merit of the project.

Administrative Review: This section of the review is concurrent with the scientific presentations; the administrative reviewer will meet with relevant RCMI personnel.

III. Scoring and Review Criteria

The context for the evaluation of an RCMI grant application is the direct impact the proposed program will have on enhancement of the applicant institution's health-related research program, based on the assessment of the specific plan proposed for achieving the overall program goals as identified by the institution. Major factors to be considered in evaluation of the application include:

A. Institutional Planning, Commitment, Goal Setting, and Evaluation

B. Program Administration including RCMI External and Internal Advisory Committees and Administrative and Financial Management

C. Environment: Institutional Capacity

D. Pilot Projects (if presented)

E. Core and Infrastructural Resources

F. Budget

Scoring: The site visit team provides a level of enthusiasm for each of the above sections (except Budget) using the NIH scale, 1 – 5, with 1 being the best possible score (to one decimal place only).

The score recommended is for scientific and technical merit (the standard NIH scale) of scientific projects:

Descriptor	Numerical Range
Outstanding	1.0 - 1.5
Excellent	1.6 - 2.5
Very good	2.6 - 3.5
Good	3.6 - 5.0
Acceptable	No Score

The RCMI-IDeA parent committee provides the final score of an RCMI application, except in cases of Special Emphasis Panels (SEP), for which the SEP does the final scoring at the site visit. The site visit team recommends a number of years for the proposal. The site visit team will also assess the appropriateness of the requested budget and allocation of required resources. Reviewers should provide an explanation for any reduction or deletion in the requested budget. Should there be a difference of opinion, the majority vote carries.

Review Criteria:

A. **Institutional Planning, Commitment, Goal Setting and Evaluation**

For all applications:

- Short- and long-term strategic planning process with clearly stated vision and goals for research growth and detailed descriptions of strategies by which to meet them
- Institutional commitment to biomedical research and training and to the RCMI program
- Organizational changes, if any, designed to enhance institutional biomedical research activities
- Identification and prioritization of major research development areas within the context of the institution and adequacy of the planning process and self-assessment of current biomedical research capabilities
- Major organizational changes that enhanced biomedical and behavioral research
- Plans for reasonable expansion of biomedical research capacity within the time-frame proposed and for sustaining this enhanced capacity beyond the period of the grant support
- Rationale and need for requested resources to achieve institutional RCMI goals, including the potential for developing and sustaining high-quality research programs

- Extent to which Program activities are multi-departmental and multi-categorical and promote interaction among investigators from multiple basic and clinical departments
- The consistency of the RCMI scientific initiatives with the institutional progress toward short- and long-term strategic plans for the RCMI program, in particular, and for the institutional research enterprise, in general

Background (one single-spaced page maximum):

- Organization and general administration, including administrative and financial structure of the institution
- Types of schools associated with biomedical infrastructure, in general, and the RCMI Program, in particular
- Approximate size of the faculty
- Institutional reporting structure and lines of responsibility, as related to the administration of the RCMI grant
- Types of degrees offered
- Number of students, fellows, interns, etc., being trained
- Relationship of the institution to the state or local government (if appropriate), or its relationship to any other entity

For new applications:

- Institutional history that is relevant to the proposed RCMI program
- How the current request builds upon institutionally-defined vision and goals for research
- Detailed and thorough description of the current status of the institution's research infrastructure, capabilities and activities
- Vision, goals, and strategies for research development
- Baseline data on the institution's current research infrastructure and programs that could potentially benefit, must be included in new applications

For competing continuation and supplemental applications:

- Specific examples of how RCMI goals were achieved in terms of enhancing biomedical research and increase in number of independently funded investigators
- If prior goals were not fully achieved, indicate plans to overcome potential institutional barriers to shortcoming
- Institutionalizing previously funded RCMI Program initiatives (moving these programs to the institutions' support mechanism for further continuation and strengthening).
- Administrative and financial management
- Scientific highlights/accomplishments
- Institutional impact of the RCMI programs and activities on biomedical research
- Describe administrative changes (PI, PD, etc.) since the last review of the RCMI and note changes made in response to prior critiques

For amended applications:

- For amended applications, response of the present application to the prior critiques

Formative and Summative Evaluation Plans

In addition to the measures of institutional infrastructure as indicated above, every proposed RCMI Program must include formative and summative evaluation plans in the application that provide details on how the institution will evaluate whether the RCMI achieved its goals and objectives as well as the RCMI progress and effectiveness. The emphasis of the evaluation activities for the RCMI Program should be on the improvement of the program and capacity-building at the institution. Improvement of the program is defined by the specific goals and measurable objectives each institutions set as part of RCMI program planning.

The institution must identify an independent evaluator, not a part of the RCMI program, who will perform the evaluation. Funds to support evaluation activities may be requested in the RCMI grant budget proposal. The completed evaluation plan should be included as a major section of the proposal.

- Appropriateness of an institutional evaluation plan for all components of the RCMI program
- Consistency of long-term goals with enhancement of biomedical research and how the evaluation component of the program is functioning
- Evaluation of program administration and structure, processes, and outcomes
- Credentials of the evaluator and/or evaluation company
- Adequacy of the evaluation planning process and methods for data collection and analysis

B. **Program Administration**

For all applications:

- Organizational structure and administration of the Program, including lines of authority within the Center to accomplish stated RCMI Program goals
- The qualifications and experience of the PD and his/her ability to provide effective leadership in implementing the institutional RCMI plan and managing fiscal, facility, and scientific resources, including collaborative and consultative arrangements
- The appropriateness of the composition of the External (EAC)and Internal (IAC)Advisory Committees to provide the needed scientific and administrative guidance for the RCMI program, in part, reflected in the biographical sketches and narrative provided in the application along with relevant site visit presentations/discussions

- The breadth and depth of committee discussions reflected in IAC and EAC meeting minutes (including attendance records)
- The role of the IAC in 1) overseeing general program functioning and management and 2) critically reviewing and prioritizing RCMI core and infrastructural resources; establishment and ongoing evaluation of pilot research studies; and involvement in the organization of developmental and/or collaborative research initiatives
- Extent of involvement of the IAC and EAC in developing the RCMI center grant application and other RCMI-related grant applications
- Reporting structure of the IAC and EAC

Financial and Grants Management:

- Adequacy and appropriateness of administrative leadership and personnel for implementing and managing the personnel, fiscal, facility, and scientific resources, including collaborative and consultative arrangements
- Lines of responsibility concerning administrative matters within the Institution and RCMI
- Nature and quality of operational relationships between RCMI and institutional administrative staff
- Efficiency and effectiveness of cost accounting procedures; verification, control, and reporting of grant expenditures; and financial record keeping
- Advisory committee participation in budget planning
- Persons responsible for the authorization of grant expenditures and verification of the charges to the grant
- Identify staff involved in budget preparation for application

C. **Environment: Institutional Capacity**

- Breadth and depth of research initiatives
- Enhancement of institutional incentives and support for research development
- Plans for further developing the biomedical/behavioral research faculty, including appropriate mentoring plans and time commitments for junior faculty
- Leveraging of RCMI funds and programs
- Quality and number of biomedical/behavioral research faculty in the institution, in general, and in areas of RCMI Program-targeted emphasis
- The quality and number of new biomedical/behavioral research faculty recruited, if applicable
- Research training and mentorship recognition
- Number of graduate degrees awarded in the biomedical/behavioral sciences
- Number of postdoctoral fellows and research associates at the institution
- Number of scientific seminars and colloquia sponsored by the institution
- Number of visiting scientists, nature of interactions, and benefits gained
- Collaborative agreements with clinical facilities, community resources, industry, and/or outside research organizations

- Research productivity as measured by the number, quality, and type of peer-reviewed publications and scientific presentations
- Scientific honors and awards to faculty
- Number and types of grant applications submitted for peer-review and number funded
- Participation of faculty members in peer-review activities locally and outside of the institution
- Election to national and international professional societies
- Involvement in planning national and international scientific meetings
- Number and nature of active collaborative research activities

Physical Facility:

- Evaluate the adequacy of the space on the RCMI needed to implement the scope of research activities recommended
- Note changes that were made in the physical facility of the RCMI since the last review if A & R was requested in previous cycle
- If alterations and renovations are requested, provide an explanation for these and make recommendations to the site-visit team on the justification or the need of the RCMI for these alterations and renovations

D. **Pilot Projects**

Pilot project investigators should be evaluated for his/her potential for a productive biomedical research career. Preliminary data are not required; emphasis is placed on the feasibility of the research plan. Data gained from the pilot projects should lead to applications for independent research support, such as R-series or K-series type applications to NIH, or to other federal or state agencies, research foundations, or industry. The projects should be hypothesis-driven, with strong scientific merit, and appropriate biostatistical input. The number of years of RCMI support needed for carrying out the project should be evaluated.

Pilot projects are evaluated according to the standard NIH five review criteria. Each pilot project will be given a score for scientific and technical merit. The need and rationale for the RCMI requested resources will be evaluated.

The score is for scientific and technical merit (the standard NIH scale) of scientific projects.

Descriptor	Numerical Range
Outstanding	1.0 - 1.5
Excellent	1.6 - 2.5
Very good	2.6 - 3.5
Good	3.6 - 5.0
Acceptable	No Score

Review Criteria:

Significance of the proposed research problem being addressed; relevance of proposed project to the institutional plan for expansion of biomedical research capacity and enhanced opportunities for collaboration

Approach, including appropriateness and feasibility of research plan, specific aims, experimental design, study methods, consideration of study limitations and potential problem areas with appropriately identified alternatives, data analysis, scope, and timetable

Innovation is a significant consideration in some, though not all, types of research projects. Innovation is characterized by novel concepts, approaches, or methods, original and innovative aims, development of new study methods, tools, or technologies; or paradigms challenged. This criteria must be weighed in terms of project proposed, which is a pilot project

Investigator training and qualification, and the appropriateness of the research to the experience level of the Principal Investigator and other personnel

Environment in which the research will be performed and anticipated contribution of the environment to the probability of success of the project

Human Subjects Protections and Inclusion: As appropriate, explicit attention to human subjects protection from research risk, development of a data and safety monitoring plan (DSMP), and appropriate inclusion of women, minorities and children in research (as required in the Research Plan, Section E on Human Subjects in the PHS Form 398.

Vertebrate Animal Welfare: As appropriate, explicit attention to the **c**are and use of vertebrate animals in research (as required in Section F of the PHS Form 398 research grant application instructions.

E. **Core and Infrastructural Resources**

Core and other infrastructural resources are determined by the individual institutions and may vary widely according to the needs across institutions. Examples of resources include core laboratories, biostatistics, bioinformatics, or any other infrastructural resources described in the application. The criteria below should be applied to each individual resource.

The application and the presenters at the site visit should describe unmet need and plans for the future use of these resources that would fit in with the institutional plan. Note that a major initiative may be implemented at any time during a five-year project period provided that the application adequately describes unmet

need(s) and describes specific plans for the future use of the resource that is consonant with the institutional biomedical research goals.

For all applications:

- Rationale and need for the resource to achieve institutional RCMI goals, including the potential for establishing a high-quality research program
- Appropriateness of the plan for managing resource utilization, including objectives, implementation strategy and timetable, SOP for use and management of the facility, quality control measures, and involvement of both the Internal and External advisory committees in prioritizing activities and judging success of operations according to clearly established evaluation criteria
- Importance of the facility to the research of the faculty, including RCMI-supported pilot projects and research by Center faculty that is supported from other sources
- Number of different investigator groups and qualifications of investigators utilizing the core facility
- Number of projects or protocols that utilize the core facility, including the demonstrated need for current or requested equipment (the existence of a current and/or projected user community is critical)
- Qualifications and expertise of the director of the core facility and other personnel
- Education in the ethical conduct of research in core activities—not limited to, but including IRB, IACUC, privacy, confidentiality, conflict of interest, and good clinical practice standards
- Training activities to be made available to investigators and personnel
- Information technology infrastructure processes and security
- Acquisition, maintenance, and utilization of major instrumentation
- Development of new or enhanced research and biotechnological capabilities (give examples
- Improvement, expansion, and location of the facilities dedicated to biomedical/behavioral research
- Justification for duplication of effort, if present in the institution
- Reasonableness of plans to institutionalize support for this resource after adequate maturity with RCMI funding (taking over the responsibility of this support)
- Suitability of location and space allotment and configuration

For competing continuation and supplemental applications:

- Evaluation of prior use of resource(s) and continued need for the resource(s)
- Assessment of progress toward prior goals for the infrastructure component
- Any re-organization/re-configuration of the resource since the last review

F. **Budget**

- Appropriateness of the requested budget and proposed project period--a complete and detailed budget and budget justification is necessary for each subsection of the application and must be in agreement with the Overall Summary Budget
- Adequacy of the evaluation budget for the planned data collection and analysis